

REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 1, 2, 5-21, 23-26 and 28-59 are in the case.

I. ELECTION /RESTRICTIONS

The election of Group I and the species recited in the first complete paragraph on page 2 of the Action are affirmed. Claims 8-13, 15, 28-31, 34-41, 345, 46 and 59 are withdrawn from consideration.

II. CLAIM OBJECTIONS

Claims 3 and 4 have been objected to as substantial duplicates. In response, claims 3 and 4 have been canceled without prejudice.

Claim 50 has been objected to as containing typographical errors. Claim 50 has been amended accordingly.

III. THE 35 U.S.C. §112, SECOND PARAGRAPH, REJECTIONS

Claims 22 and 27 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, and without conceding to this rejection, claims 22 and 27 have been canceled without prejudice.

Claims 42-44 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject

RAJ, et al.
Appl. No. 10/557,196
December 22, 2008

matter which applicant regards as the invention as claims 42-44 are dependent on claim 1, but do not start with "The". Claims 42-44 have been amended accordingly.

Claims 1-7, 17-27, 42-44, and 47-58 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Action asserts that since claims 1-7, 17-27 and 42-58 are drawn to the use of a composition comprising triprolidine in combination with at least one further active pharmaceutical agent, the claim is unclear in that it does not set forth any steps involved in the method/process.

In response, the claims have been drafted in method format, and now set forth the intended step(s). Withdrawal of the formal rejection is respectfully requested.

IV. THE 35 U.S.C. §101 REJECTION

Claims 1-7, 17-27, 42-44, and 47-58 are rejected under 35 U.S.C. 101 because the claimed recitation of a use. In response, the claims are now presented in method format. Withdrawal of the rejection is respectfully requested.

V. THE ANTICIPATION REJECTIONS

Claims 14, 16, and 32-33 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by US Patent 5,025,019. Claims 14, 16, and 32-33 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by US Patent Application Publication 2002/0058642. The rejections are respectfully traversed.

RAJ, et al.

Appl. No. 10/557,196

December 22, 2008

At the outset, it is noted that claims other than claims 14, 16, and 32-33 are not rejected on prior art grounds. It is assumed therefore that the claims not rejected on prior art grounds are free of the prior art.

Claim 14 provides a waking refreshed aid comprising triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient in association with a pharmaceutically acceptable carrier therefor and instructions for administration thereof at or just before the desired sleeping time.

US 5,025,019 discloses compositions for the treatment of cough and cold. There is no disclosure that the compositions described therein can be used as a sleeping aid which enables an individual to wake refreshed after sleeping. There is no disclosure of instructions for administration thereof at or just before the desired sleeping time.

With reference to the instructions, the Action asserts that printed matter on a label or package insert of a kit or container does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture since there is "no functional relationship between the label or package insert of a kit and the product, composition, or article of manufacture of a kit or container." However, in the claimed invention, the instructions are for administration of the actives "at or just before the desired sleeping time". In light of this, it is believed that there is a "functional relationship between the label or package insert of a kit and the.....composition...." US 5,025,019 is not therefore anticipatory of the presently claimed invention.

US200210058642 discloses compositions which require the inclusion of a glucosamine material. However, none of the exemplified compositions in this reference includes triprolidine. Moreover, there is no disclosure of instructions for administration

RAJ, et al.
Appl. No. 10/557,196
December 22, 2008

thereof at or just before the desired sleeping time. Again, as argued above, in the presently claimed invention, the instructions are for administration of the actives "at or just before the desired sleeping time". There is therefore a "functional relationship between the label or package insert of a kit and the.....composition...."

US200210058642 does not anticipate the presently claimed composition. Withdrawal of the anticipation rejections is respectfully requested.

VI. DOUBLE PATENTING

Claims 14, 16, and 32-33 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as allegedly unpatentable over claims 48 and 57 of copending Application No. 10/448,455. In response, it is requested that this rejection be placed in abeyance until the outcome of prosecution of the present application and that of 10/448,455 are known. At that time, applicants will consider whether a terminal disclaimer should be presented.

Favorable action is awaited.

Respectfully submitted,

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